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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,056	09/11/2003	William H. Fissell IV	UM-08332	7294

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EXAMINER

LAWRENCE JR, FRANK M

ART UNIT	PAPER NUMBER
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1724

DATE MAILED: 07/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/660,056

Applicant(s)

FISSELL ET AL.

Examiner

Frank M. Lawrence

Art Unit

1724

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-45 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 10-12 and 22-44 is/are allowed.
6) ☒ Claim(s) 1-4, 7, 8, 19, 21 and 45 is/are rejected.
7) ☒ Claim(s) 5, 6, 9, 13-17 and 20 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 45 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new claim 45 was not disclosed in the specification as filed. While the specification discloses manufacturing an array of membranes, it fails to disclose placing an array inside of a housing.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Keller et al. (5,948,255).
5. Keller et al. '255 teach a microfabricated ultrafiltration system, comprising a membrane including elongated micromachined pores having a length in the range of 1-1000 microns and a width of 5-100 nanometers, a housing containing the membrane, and a fluid delivery passage

Art Unit: 1724

through the housing to deliver fluid across the membrane. The membrane filter width is in the range of 1-3 mm, allowing the housing length and width to be less than 300 mm (see abstract, figures, col. 12, line 52 to col. 13, line 23, claims 1-7).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. '255.

8. Keller et al. '255 disclose all of the limitations of the claim except that the housing contains an array of the membranes. It is submitted that the multiplying of a structure to achieve an improvement in its desired effect is an obvious modification, see *St. Regis Paper Company v. Bemis Company, Inc.*, 193 USPQ 8, 10. One having ordinary skill in the art at the time of the invention would have known to multiply the number of membranes used in the housing in order to achieve a higher level of filtration, or to reduce the pressure drop by providing a larger filtration area.

9. Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Rijn (5,753,014) in view of Keller et al. '255.

10. Van Rijn '014 discloses a micromachined, biocompatible ultrafiltration membrane that can be used to filter blood *in vivo* without using a pump (see abstract, col. 1, lines 50-56, col. 2, lines 44-58, col. 5, lines 1-34, col. 13, lines 3-14). The instant claims differ from

Art Unit: 1724

the disclosure of Van Rijn '014 in that the membrane is inside of a biocompatible housing having preferred dimensions.

11. Keller et al. '255 disclose a membrane filtration housing as described in paragraph 5 above. Although Van Rijn '014 fails to explicitly disclose the use of a housing with the membrane, one having ordinary skill in the art would understand that some type of housing would be required to conduct fluid to and away from the membrane, and that the housing would necessarily be biocompatible for *in vivo* use. One skilled in the art would have looked to Keller et al. '255 for a housing structure that could be used with micromachined ultrafiltration membranes.

Allowable Subject Matter

12. Claims 10-12 and 22-44 are allowed.

13. The following is an examiner's statement of reasons for allowance: Reasons for allowance of claims 10-12 and 22-35 are given in the previous office action, which also apply to claims 36-44.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

14. Claims 5, 6, 9, 13-17 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

15. Applicant's arguments filed June 13, 2005 have been fully considered but they are not persuasive. In response to applicant's argument that the Keller et al. '255 patent fails to disclose a membrane that is configured to receive blood or plasma from a subject's vasculature, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). In this case, the prior patent discloses a membrane filter in a housing with flow passages capable of carrying any fluid type, wherein the filter has pore sizes disclosed with sufficient specificity to anticipate the recited porous membrane of the instant invention.

16. With respect to applicant's arguments that the combination rejection over Keller et al. and Van Rijn, the examiner finds them persuasive and has withdrawn the rejection of claim 13 and its dependents because the Van Rijn patent teaches away from using elongated pores in blood filtration. A new rejection of claim 19 with Van Rijn as the primary reference is presented to address the amendment to the claim.

17. The previous indefiniteness rejection and objection to the specification have been overcome and are withdrawn.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank M. Lawrence whose telephone number is 571-272-1161. The examiner can normally be reached on Mon-Thurs 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Duane Smith can be reached on 571-272-1166. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1724

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank M. Lawrence
Primary Examiner
Art Unit 1724

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Frank Lawrence
7-18-05